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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,268

03/19/2002

Christian Kropf

H 4086 PCT/US

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10/05/2006

DANN DORFMAN HERRELL AND SKILLMAN
A PROFESSIONAL CORPORATION
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

GRAFFEO, MICHEL

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,268

Applicant(s)

KROPF ET AL.

Examiner

Michel Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17,20,21,28 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,17,20,21,28 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 31 July 06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 16-17, 20-21, 28 and 31-37 are examined.

Applicant has amended claim 16, canceled claims 18-19, added claims 33-37 and provided arguments for the patentability of claims 16-17, 20-21, 28 and 31-37 in the response filed 5 July 2006.

Applicant's arguments, see response, filed 5 July 2006, have been fully considered but are not persuasive. Examiner notes Applicants intention to address the Double Patenting rejections upon allowance. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 20-21, 28 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over PCT/IB97/01634 to Rudin *et al.* in view of US Patent No. 4,933,173 to Bristow *et al.*

Rudin *et al.* teach a hydroxyapatite composite comprising finely divided rod like particles of hydroxyapatite having dimensions of 60nm (L) by 15nm (W) by 5nm (T) (see page 2 paragraph 5) and a surfactant (see page 4 paragraph 4 and Example 5 which includes polyethylene glycol) which can be used to prepare toothpastes (see Abstract).

Rudin *et al.* do not teach the incorporation of a protein, protein hydrolyzate or protein hydrolyzate derivative into the composite.

Bristow *et al.* teach an oral preparation for example a toothpaste comprising hydroxyapatite and casein and explain that casein is an anti-caries agent (see col 1 lines 13-16) and additional proteins such as those from nuts (see col lines 40-50) and has a high degree of compatibility with hydroxyapatite, which is present in an amount of from 0.01% to 10% (see col 1 lines 50-55).

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One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the above references because Bristow et al. teach that hydroxyapatite and casein are compatible and further that casein has anti-caries properties, both of which are reasons to add casein to a toothpaste and cause one of ordinary skill in the art to expect a better product. Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Response to Amendment - 35 USC § 103

Applicant's arguments filed 5 July 2006 have been fully considered but they are not persuasive. Applicants argue that the claims have been amended to remove casein from the list of proteins in the claims. That notwithstanding, the Bristow et al. reference as shown above lists other proteins such as those from nuts (almond is a nut and therefore would have been obvious to one of ordinary skill in the art), vegetables etc. Additionally, Applicants argue that one of ordinary skill in the art would not have been motivated to combine the references. In addition to the motivation outlined above, both references are directed to oral care products such as toothpastes and without a reason in the references for not combining them other than the ingredients are not completely the same is insufficient. In other words, Applicant's arguments that since Bristow et al. discuss a toothpaste substantially free of fluoride does not mean that the fluoride if used in Rudin et al. is uncombinable especially in light of the product made, toothpaste, and

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that fluoride is typically used in toothpastes. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Maintained Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-17, 20-21, 28 and 31-37 are provisionally rejected under the judicially created doctrine of double patenting over claims 8-10 and 13 of copending Application No. 09/868,379. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-17, 20-21, 28 and 31-37 of the instant application and claims 8-10 and 13 of copending Application No. 09/868,379.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 09/868379 reference
16/33	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of 10-50nm diameter particles and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
17/36	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives. Since the particle is rod-like, it would be obvious to one skilled in the art that thickness is equal to diameter.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and length of 10 to 150nms and a water-soluble polymeric protective colloid adsorbed onto said particle which can be for example casein or gelatine. See also Claims 9, 10 and 13.
20/34	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle. See also Claims 9, 10 and 13.
21/35	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 8: A phosphate, fluoride or fluorophosphate calcium salt in form of particles having a diameter of 10-50nm and a water-soluble polymeric protective colloid adsorbed onto said particle, which can be a protein for example casein or gelatine. See also Claims 9, 10 and 13.
28	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein	Claim 13: A toothpaste comprising a one or more calcium phosphate, hydroxylapatite, fluorapatite or calcium fluoride wherein the salt particles have diameters from 5-50 nm and a water-

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	derivatives.	soluble polymeric protective colloid adsorbed onto said particle wherein such colloid can be a protein such as casein or gelatine.
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Claims 16-17, 20-21, 28 and 31-37 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-8 of copending Application No. 10/465157. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-17, 20-21, 28 and 31-37 of the instant application and claims 1-8 of copending Application No. 10/465157.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 10/465157 reference
16/33	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. See also Claims 1-3 and 5-8 to the extent that the salt particles are finely divided and finely divided can to one skilled in the art include those

		particles with a 10-300nm fineness. Further the specification of this reference states on page 5 that "Those only slightly water-soluble calcium salts have proven particularly advantageous which have a mean particle fineness of 10-300 nm (nanometers)."
17/36	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-3 and 6-8.
20/34	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine. Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-3 and 6-8. This application does not claim surface modifiers, but surface modifiers can be emulsifiers, colloids and surfactants all of which are traditionally used in dental materials and excipients (See <i>Kirk-Othmer Encyclopedia of Chemical Technology</i> Copyright © 1993 by John Wiley & Sons, Inc. All rights reserved. DOI: 10.1002/0471238961.0405142016010405.a001 Article Online Posting Date: December 4, 2000.)
21/35	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 5: A finely divided phosphate, fluoride or fluorophosphate calcium salt and a protein which can be for example casein or gelatine. See also Claims 1-4 and 6-8.
28/33	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles	Claim 4: A phosphate, fluoride or fluorophosphate calcium salt having a mean particle fineness of 10-300nm and a water-soluble or swellable support material which can be for example casein or gelatine.

	and a protein or protein derivatives.	See also Claims 1-3 and 5-8. This reference does not recite a toothpaste in any claim preamble but instead recites a dental adhesive for local remineralizing tooth treatment. It would be obvious to one skilled in the art to use the reference as a toothpaste since, as the applicant admits in its specification on page 1, "Phosphate salts of calcium have long been added to the formulations of tooth cleaning and dental care preparations both as abrasive components and for promoting the remineralizing of dental enamel." Thus it would be obvious to use the dental adhesive as a toothpaste and the dental adhesive is an obvious variation on a toothpaste.
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Claims 16-17, 20-21, 28 and 31-37 are provisionally rejected under the judicially created doctrine of double patenting over claims 20-27 of copending Application No. 10/297,889. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-17, 20-21, 28 and 31-37 of the instant application and claims 20-27 of copending Application No. 10/297,889.

Claim Number	Claim limitations from '268	Limitations claimed in 10/297,889 reference
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(10/030268)		
16/33	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27.
17/36	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27.
20/34	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	Claim 20: A phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-27. This application does not claim surface modifiers, but surface modifiers can be emulsifiers, colloids and surfactants all of which are traditionally used in dental materials and excipients (See <i>Kirk-Othmer Encyclopedia of Chemical Technology</i> Copyright © 1993 by John Wiley & Sons, Inc. All rights reserved. DOI: 10.1002/0471238961.0405142016010405.a001 Article Online Posting Date: December 4, 2000.)
21/35	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	Claim 21: Hydroxyapatite and fluoroapatite having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 20, 22-27.
28/33	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles	Claim 20: A composition for treating tooth and/or bone, of which includes toothpaste, comprising a phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a

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	and a protein or protein derivatives.	protein (see Dictionary in AccessScience@McGraw-Hill). Claim 27: A paste comprising a phosphate, fluoride or fluorophosphate calcium salt having an average particle diameter of from 5-300nm and a polyelectrolyte which can be a protein (see Dictionary in AccessScience@McGraw-Hill). See also claims 21-26.
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Claims 16-17, 20-21, 28 and 31-37 are provisionally rejected under the judicially created doctrine of double patenting over claims 20-27 of copending Application No. 10/297,842. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows in the table of comparison below:

Table of comparison between claims 16-17, 20-21, 28 and 31-37 of the instant application and claims 20-27 of copending Application No. 10/297,842.

Claim Number (10/030268)	Claim limitations from '268	Limitations claimed in 10/297,842 reference
16/33	A phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein	Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine.

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	derivatives.	This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.
17/36	A phosphate, fluoride or fluorophosphate calcium salt in form of rod-like particles having a thickness of 2-50nm and a length of 10-150nm and a protein or protein derivatives.	<p>Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine.</p> <p>This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported. The diameter is a function of the shape of the particle of for example hydroxyapatite which crystallizes into hexagonal rhombic prisms i.e. rod-like and thus a diameter of 1-200nm would correspond to a length within the range of 10-150nm (See S. Zhang and K.E. Gonsalves, J. Mater. Sci. Mater, Med. 8 (1997) 25.)</p>
20/34	A calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives wherein the salt is encapsulated with one or more surface modifiers.	<p>Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine.</p> <p>This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.</p>
21/35	Hydroxylapatite or fluorapatite in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	<p>Claim 21: An oral or dental care composition comprising nanoparticulate particles hydroxides, carbonates and phosphates which include for example, hydroxylapatite and fluorapatite, and a surface modifying agent which includes a protein such as casein or gelatine.</p> <p>This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.</p>
28/33	A toothpaste comprising a phosphate, fluoride or fluorophosphate calcium salt in form of 10-300nm diameter rod-like particles and a protein or protein derivatives.	<p>Claim 21: An oral or dental care composition, of which a toothpaste is, comprising nanoparticulate particles hydroxides, carbonates and phosphates for example, and a surface modifying agent which includes a protein such as casein or gelatine.</p> <p>This claim does not recite the specific particle size, but on page 4 of the specification, a diameter range from 1-200nm is supported.</p>

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28 September 2006

MG

Ardin H. Marschel 9/29/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER